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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

STEPHANIE WILHITE, o/b/o The Estate of Linda Wilder,	)	
Plaintiff,	)	
	)	Case No. 2:23-cv-00423-SGC
v.	)	
MEDTRONIC, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION[1]

This is a products liability action brought against Medtronic, Inc., by Stephanie Wilhite, proceeding on behalf of the Estate of Linda Wilder. The matter is before the court on Medtronic's motion to dismiss the amended complaint. (Doc. 11).[2] For the reasons stated below, the motion is due to be granted, and this action is due to be dismissed with prejudice.

I. Procedural History

Wilhite commenced this action in the Circuit Court of Jefferson County, Alabama. (Doc. 1-1). Medtronic removed the action to this district court on the basis of diversity jurisdiction and then filed a motion to dismiss Wilhite's claims as

[1] The parties have consented to the exercise of dispositive jurisdiction by a magistrate judge pursuant to 28 U.S.C. § 636(c). (Doc. 13).

[2] Citations to the record refer to the document and page numbers assigned by the court's CM/ECF electronic document system and appear in the following format: (Doc. __ at __).

insufficiently pleaded and, alternatively, preempted by federal law. (Docs. 1, 3). Wilhite responded by filing an amended complaint, effectively mooting Medtronic's motion to dismiss because that motion addressed what was no longer the operative pleading. (Docs. 8, 10). Medtronic then filed a motion to dismiss the claims asserted in the amended complaint as preempted by federal law and, alternatively, insufficiently pleaded. (Doc. 11). The motion has been fully briefed. (Docs. 15, 16).

II. Allegations of Amended Complaint

Medtronic designed, manufactures, and sells the Evera XT DR Defibrillator (an "Evera" or the "Evera"). (Doc. 8 at ¶ 18). The Evera is a Class III medical device regulated by the U.S. Food and Drug Administration (the "FDA"). (Doc. 8 at ¶ 9).

Wilhite alleges the design and manufacturing of the Evera was defective and the testing of the device before placing it on the market was inadequate, insofar as the defibrillator was susceptible to a rapid and unexpected decrease in battery life that could result in full battery depletion within as little as one day. (Doc. 8 at ¶ 76). She alleges Medtronic knew or should have known of the defect before placing the Evera on the market, failed to provide adequate warnings regarding the issue to the FDA or the public, and instead disseminated false and misleading information regarding the reliability and longevity of the Evera and minimized the risks

associated with the defibrillator. (Doc. 8 at ¶¶ 6, 11, 29-31, 35, 42-46, 50, 52-53, 76, 81). Wilhite asserts Medtronic had "a continuing duty to comply with the requirements listed in [its] PMA and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, testing, and sale of [the Evera]" and cites 24 sections from the Code of Federal Regulations, "[v]iolations [of which] also constitute violations of [Medtronic's] parallel state duties." (Doc. 8 at ¶¶ 62, 63).[3]

Medtronic recalled the Evera on February 3, 2021, due to the battery issue described above. (Doc. 8 at ¶ 7). Wilhite alleges the recall should have come sooner. (Doc. 8 at ¶ 76(d)). Wilder, who had an Evera implanted on an unspecified date prior to the recall, died on April 5, 2021. (Doc. 8 at ¶¶ 6, 8). Her physician determined her death was caused by the failure of her Evera – more specifically, that there was an issue with the Evera's generator or that the Evera "went through its full prescription and stopped shocking." (Doc. 8 at ¶ 8).[4]

Based on these allegations, Wilhite asserts a claim against Medtronic under the Alabama Extended Manufacturer's Liability Doctrine (the "AEMLD") and claims for negligence, negligence *per se*, wantonness, and breach of implied

[3] As discussed below, "PMA" is shorthand for "premarket approval," a process of review that a medical device for human use must pass before being placed on the market. "FDCA" refers to the 1938 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

[4] As of March 22, 2021, Wilder's defibrillator indicated it had 2.2 years of remaining battery life. (Doc. 8 at ¶ 8).

warranty under Alabama law. Wilhite does not assert a standalone fraud claim. However, as stated, she alleges Medtronic made false representations regarding the reliability and longevity of the Evera and concealed information about the risk of rapid and unexpected battery depletion. In the interest of thoroughness, the court will construe the amended complaint as asserting claims for false representation and fraudulent suppression, as well.

III. Standard of Review

Rule 12(b)(6) must be considered against the backdrop of Rule 8(a)(2) of the *Federal Rules of Civil Procedure*. Rule 8(a)(2) "requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the … claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Rule 8 "does not require 'detailed factual allegations,' but it demands more than an unadorned, the defendant-unlawfully-harmed me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009) (quoting *Twombly*, 550 U.S. at 555). "[L]abels and conclusions," "a formulaic recitation of the elements of a cause of action," and "naked assertion[s] devoid of further factual enhancement" are insufficient. *Id.* at 678 (quoting *Twombly*, 550 U.S. at 555, 557) (internal quotation marks omitted).

To survive a motion to dismiss for failure to state a claim on which relief may be granted brought pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556).

IV. Discussion

The Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360c *et seq.*, gives the FDA regulatory authority over medical devices for human use. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).[5] The FDA classifies medical devices into three categories based on the level of risk presented. *Id.* at 316-17 (citing § 360c(a)(1)). Class III is the highest risk category. *Id.* at 317 (citing § 360c(a)(1)(C)). Before a company may sell a Class III medical device, it must obtain premarket approval ("PMA") from the FDA. *Id.* (citing § 360c(a)(1)(C)). PMA "is a 'rigorous'

[5] The MDA amended the 1938 Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq.*, which requires FDA approval for the introduction of new drugs into the market. *Riegel*, 552 U.S. at 315.

process." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). A manufacturer typically must submit a multivolume application that includes:

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling . . . [which] [t]he FDA . . . must determine . . . is neither false nor misleading.

Id. at 317-18 (quoting § 360e(c)(1)). The FDA spends an average of 1,200 hours reviewing an application for PMA. *Id.* at 318. It grants approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* (quoting § 360e(d)). "The agency must 'weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id.* (quoting § 360c(a)(2)(C)). "It may thus approve devices that present great risk if they nonetheless offer great benefits in light of available alternatives." *Id.*

After obtaining PMA for a Class III medical device, a manufacturer must comply with the FDA's current good manufacturing practice requirements, which regulate " 'the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.'" *Marmol v. St. Jude Med. Ctr.*, 132 F. Supp. 3d 1359, 1363 (M.D. Fla. 2015) (quoting 21 § C.F.R. 820.1(a)(1)). A manufacturer

must obtain FDA permission before it makes a change in design, manufacturing, or labeling that would affect the safety or effectiveness of the device. *Riegel*, 552 U.S. at 319 (citing § 360e(d)). And a manufacturer must report adverse events – "incidents in which [a] device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred" – to the FDA. *Id.* (citing § 360i).

The MDA includes an express preemption provision, 21 U.S.C. § 360k(a), and an implied preemption provision, 21 U.S.C. § 337(a). The express preemption provision bars any claim based on a state law requirement that is " 'different from, or in addition to'" any federal requirement. *Riegel*, 552 U.S. at 321 (quoting § 360k(a)(1)). However, it does not bar "a damages remedy [under state law] for claims premised on a violation of FDA regulations." *Id.* at 330. "[T]he state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (citing *Lohr*, 518 U.S. at 495). This is true even if a plaintiff must prove additional elements, such as negligent conduct or the creation of an unreasonable hazard, to establish a violation of state law. "[S]uch additional elements of the state-law cause of action would make the state requirements [for a medical device] narrower, not broader, than the federal requirement," and "[w]hile such a narrower requirement might be 'different from' the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it

duplicates the federal rule." *Lohr*, 518 U.S. at 495; *cf. Wolicki-Gables v. Arrow Intern.*, 634 F.3d 1296, 1300 (11th Cir. 2011) (" 'State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.'") (quoting *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005)).

The implied preemption provision states all actions to enforce FDA requirements for medical devices "shall be by and in the name of the United States." § 337(a). "Put another way: a plaintiff cannot seek to privately enforce a duty that is owed to the FDA." *Jacob v. Mentor Worldwide, LLC*, 40 F.4th 1329, 1336 (11th Cir. 2022). "So, even if a plaintiff's claim is not expressly preempted, it is impliedly preempted if it is cognizable only because of duties owed to the FDA." *Id.* "State-law claims based on conduct that violates the [MDA] can escape implied preemption only if the alleged wrongdoing would give rise to liability under state law even if the [MDA] did not exist." *Id.*

The Eleventh Circuit has explained "express and implied preemption leave a 'narrow gap' through which a plaintiff's claim must pass to survive: 'a plaintiff has to sue for conduct that violates a federal requirement (avoiding express preemption) but cannot sue only because the conduct violated that federal requirement (avoiding implied preemption).'" *Id.* (quoting *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1327 (11th Cir. 2017)). "In other words when a plaintiff's claim implicates the

safety or effectiveness of a federally regulated medical device, her claim survives preemption 'so long as she claims the breach of a well-recognized duty owed to her under state law and so long as she can show that she was harmed by a violation of applicable federal law.'" *Id.* (quoting *Godelia v. Doe I*, 881 F.3d 1309, 1317 (11th Cir. 2018)).

A. Claims Based on Duty to Design and Manufacture Reasonably Safe Product

Wilhite's AEMLD, negligence, negligence *per se*, wantonness, and breach of implied warranty claims are based in part on Medtronic's alleged breach of the duty to design and manufacture a reasonably safe product. The court reads the amended complaint as asserting the Evera is not reasonably safe either as approved by the FDA or because the design and manufacture of the medical device deviated from FDA requirements.

The design of the Evera, including what (if any) warning to attach to the device, and its method of manufacture was approved by the FDA after a "rigorous process of [] review." *See Riegel*, 552 U.S. at 317 (describing process). Insofar as Wilhite alleges the testing, design, and manufacturing of the Evera, and the messaging accompanying the medical device, should have been different than what the FDA approved, she seeks to impose state law requirements on Medtronic that are "different from, or in addition to," the federal requirements imposed by the FDA, and her claims are expressly preempted by the MDA. *See, e.g.*, *Byrnes v. Small*, 60

F. Supp. 3d 1289, 1298 (M.D. Fla. 2015) (applying similar analysis to hold design defect claim asserted under Florida law was expressly preempted by MDA); *Horn v. Boston Scientific Neuromodulation Corp.*, 2011 WL 3893812, at *6-7 (S.D. Ga. Aug. 26, 2011) (applying similar analysis to hold breach of implied warranty claim asserted under Georgia law was expressly preempted by MDA).

A claim that a Class III medical device violated state law by deviating from an FDA requirement, unlike a claim a Class III medical device is not reasonably safe in the form approved by the FDA, is capable of escaping express preemption. A Class III medical device for which PMA has been obtained necessarily is subject to federal requirements. *Mink*, 860 F.3d at 1326 (citing *Wolicki-Gables*, 634 F.3d at 1301). It is subject to device-specific requirements promulgated under the PMA process, and it is subject to general requirements for all medical devices promulgated by the FDA. *Rosen v. St. Judge Med., Inc.*, 41 F. Supp. 3d 170, 178 (N.D.N.Y. 2014). Violation of either a device-specific requirement or a general requirement may support a parallel claim. *Mink*, 860 F.3d at 1331 n.3; *Godelia*, 881 F.3d at 1319-20; *Jacob*, 40 F.4th at 1338; *see also Lowery v. Sanofi-Aventis LLC*, 535 F. Supp. 3d 1157, 1182 (N.D. Ala. 2021) (recognizing violation of federal requirement supports claim under AEMLD and claims for negligence, negligence *per se*, and wantonness under Alabama law); *Grubbs v. Medtronic, Inc.*, 2019 WL 3288263, at *4 (N.D. Ala. July 22, 2019) (holding allegations medical device was not fit for its

intended use in light of manufacturer's failure to comply with FDA regulations supported breach of implied warranty claim under Alabama law).

But a plaintiff must assert a plausible parallel claim by alleging facts suggesting the violation of a device-specific requirement or general requirement. *See Wolicki-Gables*, 634 F.3d at 1301 ("[A]n allegation that 'the manufacturing processes for [a] device and certain of their . . . components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices' is insufficient to satisfy the requisite elements of a parallel claim as set forth in *Riegel* if the complaint fails to 'provide any factual detail to substantiate that crucial allegation.'") (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008)). "[I]f a plaintiff simply claims that a defendant violated a federal regulation without identifying [] the specific facts showing how a defendant violated either a PMA specification or a specific GMP . . . then that plaintiff fails to adequately assert a parallel claim." *Lowery*, 535 F. Supp. 3d at 1179 (citing *Wolicki-Gables*, 634 F.3d at 1301).

Appellate courts, including the Eleventh Circuit, have recognized a plaintiff may have difficulty pleading the violation of a device-specific requirement because PMA documents are confidential. *See, e.g., Godelia*, 881 F.3d at 1319; *Baush v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). " 'An injured patient cannot gain access to that information without discovery.'" *Godelia*, 881 F.3d at 1320 (quoting

Bausch, 630 F.3d at 560). This may afford a plaintiff some leniency at the pleading stage. However, it does not excuse a plaintiff from alleging facts that plausibly suggest the violation of a federal requirement. For example, the plaintiff in *Godelia* pleaded plausible parallel claims by alleging the FDA had inspected the defendant's facilities and determined the medical devices manufactured there were adulterated in violation of regulatory requirements. 881 F.3d at 1315, 1319-20. And the plaintiff in *Bausch* pleaded plausible parallel claims by alleging the FDA had inspected the defendants' manufacturing facility, informed the defendants of numerous deficiencies in manufacturing and inspection processes related to its medical device, and later warned the defendants the device was adulterated due to manufacturing methods not in conformity with regulatory standards. 630 F.3d at 558-61.

As stated, Wilhite alleges Medtronic had "a continuing duty to comply with the requirements listed in [its] PMA and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, testing, and sale of [the Evera]" and cites 24 sections from the Code of Federal Regulations, "[v]iolations [of which] also constitute violations of [Medtronic's] parallel state duties." (Doc. 8 at ¶¶ 62, 63). This amounts to no more than an oblique suggestion Medtronic violated a federal requirement capable of underpinning a parallel state claim. But the ultimate failing of the amended complaint is the absence of factual allegations accompanying the oblique suggestion. Wilhite does not allege any facts regarding

a defect in the design or manufacturing of the Evera that resulted from Medtronic's violation of a federal requirement and caused sudden battery depletion. Without factual allegations to support the plausible violation of a federal requirement, Wilhite's claims based on post-PMA conduct, like her claims based on the design and manufacture of the Evera as approved by the FDA, seek to impose state law requirements on Medtronic that are "different from, or in addition to," the federal requirements imposed by the FDA and are expressly preempted by the MDA.

B. Claims Based on Duty to Warn

Wilhite's AEMLD, negligence, negligence *per se*, and wantonness claims also are based on Medtronic's alleged breach of the duty to report adverse events involving rapid and unexpected battery depletion in the Evera to the FDA, Wilder, and her doctors. There is no federal requirement that the manufacturer of a Class III medical device report adverse events directly to the end-user or her physician. *Marmol*, 132 F. Supp. 3d at 1369. Therefore, to the extent Wilhite claims Medtronic violated the AEMLD and committed negligence, negligence *per se*, and wantonness by failing to report adverse events to Wilder and her doctors, she seeks to impose state law requirements on Medtronic that are "different from, or in addition to," the federal requirements imposed by the FDA, and the claims are expressly preempted by the MDA. *See McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1199-1200 (M.D. Fla. 2013) (holding negligence claim based on alleged failure to warn patients

of adverse events involving Class III medical device was expressly preempted by MDA); *Byrnes*, 60 F. Supp. 3d at 1297 (holding fraud claims based on alleged failure to warn medical community of dangers associated with off-label use of Class III medical device were expressly preempted by MDA).

As discussed, there is a federal requirement that the manufacturer of a Class III medical device report adverse events to the FDA. However, the court is not aware of a corresponding requirement under Alabama law. *See Grubbs*, 2019 WL 3288263, at *3 (noting the court had found no authority for the proposition that Alabama law imposes a duty on medical device manufacturers to warn a federal agency of dangers associated with a device). Therefore, to the extent Wilhite claims Medtronic violated the AEMLD and committed negligence, negligence *per se*, and wantonness by failing to report adverse events to the FDA, she seeks to enforce a duty owed only to the FDA, and her claims are impliedly preempted by the MDA. *See McClelland*, 944 F. Supp. 2d at 1200-01 (holding negligence claim based on alleged failure to report adverse events involving Class III medical device to FDA was impliedly preempted by MDA); *Byrnes*, 60 F. Supp. 3d at 1297 (holding fraud claims based on alleged failure to report adverse events involving Class III medical device to FDA were impliedly preempted by MDA).

C. Claim Based on Duty to Recall

In the context of her wantonness claim, Wilhite alleges Medtronic should have recalled the Evera sooner. (Doc. 8 at ¶ 76(d)). There is no duty to recall under Alabama law. *Harris v. Raymond Corp.*, 2018 WL 6725329, at *9 (N.D. Ala. Dec. 21, 2018) (citing *Lampley v. Bridgestone Firestone, Inc.*, 1992 WL 12666661, at *1 (M.D. Ala. Mar. 31, 1992)). Wilhite does not identify a federal recall requirement, either. Accordingly, to the extent Wilhite's wantonness claim is based on Medtronic's alleged failure to recall the Evera in a timely manner, it is due to be dismissed for failing to state a claim on which relief can be granted.

D. False Representation & Fraudulent Suppression Claims

A false representation constitutes actionable legal fraud, whether made willfully, recklessly, or by mistake. *See* Ala. Code § 6-5-101 ("Misrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud."); *Bryant Bank v. Talmage Kirkland & Co.*, 155 So. 3d 231, 235 (Ala. 2014) (interpreting § 6-5-101); *Lawson v. Harris Culinary Enterprises, LLC*, 83 So. 3d 483, 492 (Ala. 2011) (same). Consequently, a false representation claim of any of the three varieties must comply with the requirement of Rule 9(b) of the *Federal Rules of Civil Procedures* that fraud be pleaded with particularity. *See Austin v. Regency Realty*, 2024 WL 69902, at *6

(M.D. Ala. Jan. 5, 2024) (applying heightened pleading standard articulated in Rule 9(b) to false representation claim). The same is true for a fraudulent suppression claim. *See* Ala. Code § 6-5-102 ("Suppression of a material fact which the party is under an obligation to communicate constitutes fraud."); *Franklin Cnty. Comm'n v. Madden*, 2019 WL 4143042, at *5 (N.D. Ala. Aug. 30, 2019) (applying heightened pleading standard articulated in Rule 9(b) to fraudulent suppression claim).

To plead fraud with the particularity required by Rule 9(b), a plaintiff must allege "precisely" what misrepresentation was made in, or what fact was omitted from, what document. *Brooks v. Blue Cross and Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1371 (11th Cir. 1997). She also must allege the time and place of the misrepresentation or omission. *Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010). These are not the only requirements of the particularity required by Rule 9(b). *See id.* (articulating additional requirements); *Brooks*, 116 F.3d at 1371 (same). The court highlights these requirements because they are the ones on which Wilhite's fraud claims fail. Wilhite does not allege the substance of any alleged false representation made by Medtronic with respect to the reliability and longevity of the Evera. The portions of her amended complaint construed collectively as asserting a false representation claim are limited to the repetition of vague and general allegations and legal conclusions. *See Rowe v. Mentor Worldwide, LLC*, 297 F. Supp. 3d 1288, 1297 (M.D. Fla. Mar. 2, 2018) (holding "[a]

brief review" of allegations underlying negligent misrepresentation claim, similar to allegations underlying Wilhite's false representation claim, showed they were "wholly inadequate" to satisfy the Rule 9(b) pleading standard). Wilhite likewise fails to allege when or where any alleged false representation was made or when or where omission of the risk of rapid and unexpected battery depletion in the Evera was made. Absent these allegations of fact, Wilhite falls short of stating a plausible claim for false representation or fraudulent concealment. The court need not reach the question of whether the claims would be preempted if sufficiently pleaded.

V. Conclusion

For the reasons stated above, Medtronic's motion to dismiss (Doc. 11) is due to be granted, and this action is due to be dismissed with prejudice.[6] A separate order will be entered.

[6] Generally "[w]here a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice." *Bank v. Pitt*, 928 F.2d 1108, 1112 (11th Cir. 1991), *overruled in part by Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002). Although Wilhite has had an opportunity to file an amended complaint, that pleading was filed as "a matter of course" and, therefore, cannot be considered as a prior opportunity to amend for purposes of dismissing all of her claims with prejudice. *See* Fed. R. Civ. P. 15(a) (allowing amendment of complaint as "a matter of course" within 21 days after service of Rule 12(b) motion and, thereafter, only with leave of court); *Bryant v. Dupree*, 252 F.3d 1161, 1163-64 (11th Cir. 2001) (holding plaintiff could not be considered to have been given prior opportunity to amend where amended complaint was filed as "a matter of course"). However, in *Wagner*, the Eleventh Circuit modified the *Bank* rule to the extent a plaintiff is represented by counsel and does not request leave to amend. The appellate court held that, under those circumstances, a district court is not required to afford a plaintiff leave to amend *sua sponte*. *Wagner*, 314 F.3d at 542. Wilhite is represented by counsel and has not requested leave to further amend her complaint.

DONE this 6th day of March, 2024.

Staci G. Cornelius

STACI G. CORNELIUS
U.S. MAGISTRATE JUDGE